

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant : Robert T. Tranquillo et al
Serial No. : 10/562,955
Filed : August 3, 2006
Title : Engineered Blood Vessels
Art Unit : 1651
Attorney Docket : 890003-2008.1

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Robert T. Tranquillo, Ph.D., declares and states:

I am Distinguished McKnight University Professor and Head of Biomedical Engineering at The University of Minnesota, the owner of the above-captioned patent application, U.S. Application No. 10/562,955, which is a national stage filing under 35 U.S.C § 371 of PCT/US04/21414, filed July 1, 2004, and claims priority to provisional Application No. 60/484,563, filed July 1, 2003, and provisional Application No. 60/484,595, filed July 2, 2003, entitled "Engineered Blood Vessels."

I am the subject of the attached Curriculum Vitae and author of the publications listed in the attachment. On the basis of the information and facts contained in these documents I submit that I am an expert in the field of cardiovascular tissue engineering and have published papers on the fabrication of tissue-engineered arteries. I believe that I am qualified to speak on the skill and knowledge of the person of ordinary skill in these fields.

I have read and understand the subject matter of the above-captioned patent application. I have read and understand the final Office Action dated June 10, 2009, and the Advisory Action dated December 21, 2009, rejecting claim 59-67 and 77 as being unpatentable over the references listed below. I have read and understand these references. These include Shum-Tim et al., *Ann Thorac Surg* 68:2298 (1999) (herein “Shum-Tim”); U.S. 5,792,603 to Dunkelman (herein “Dunkelman”); Mitchell et al., *Cardiovascular Pathology*, 12:59 (2003) (herein “Mitchell”); Henrikson (Ed.), *Histology* (1997) (herein “Henrikson”); and U.S. 6,387,663 to Hall (herein “Hall”).

Applying the Shum-Tim Graft to the Dunkelman Apparatus Would Not Produce The Claimed Invention

The claims describe the use of (chemo)attractants and/or mitogens in the solution in the lumen of the vascular construct. The purpose for their inclusion is for diffusion from the lumen into the construct, establishing a concentration gradient that will inducing the endothelial cells to localize at the luminal surface by chemotaxis (directed cell migration toward the source of the chemoattractant, in this case the luminal surface) and/or proliferation. It is well known that a chemotaxis response is greatest when the concentration gradient of a chemoattractant is steepest. Similarly, the localizing effect due to differential proliferation will be greatest when a concentration gradient of a mitogen is steepest. Establishing the steepest possible concentration gradient within the vascular construct is thus indispensable to the cellular processes upon which the claims are based.

It is well known that the effect of fluid flow across space in which a concentration gradient exists due to diffusion is to reduce the steepness of the gradient when the flow is in the down gradient direction. This is clearly seen in Fig. 7.3 of “Transport Phenomena in Biological Systems: A Textbook for Biomedical Engineers” by G. A. Truskey, F. Yuan and D. F. Katz, 2nd edition where for increasing flow (increasing Pe), the concentration gradient the source of the diffusing chemical (i.e. the slope of the curve at $z/L=0$) is reduced – see below.

The Dunkelman process involves pressurizing the fluid in the lumen resulting in convective flow outward through the construct, termed transmural flow (see below for detailed analysis). This situation is exactly what the aforementioned Figure analyzes, where $z/L=0$ is the luminal surface (located next to the source of the attractants and/or mitogens in the lumen), showing the transmural flow that is intrinsic to the Dunkelman bioreactor would undermine establishing the concentration gradients of attractants and/or mitogens that is essential to the claims of this application.

Analysis of U.S. Patent 5,792,603 by Dunkelman et al. in order to assess the bioreactor's ability for allowance of transmural flow.

In order for transmural flow to occur, two conditions must be met: a porous medium (in this case, fluid has to be able to flow radially) and a pressure gradient.

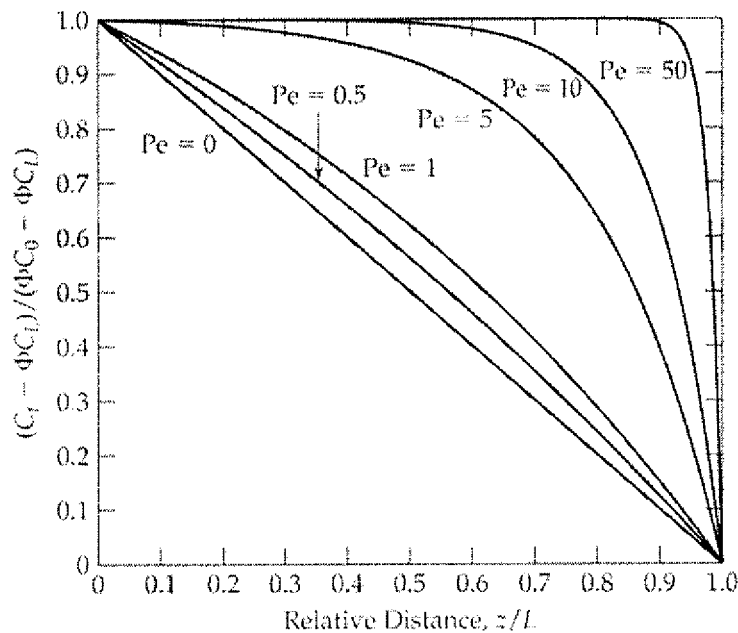
Multiple embodiments of the invention are present: in the embodiments portrayed in FIGs. 1, 3, 4, the graft scaffolding is placed on an expandable tube. While the permeability of the tube is not specified in the description for FIGs. 1 and 3, "porous tube 48" (column 5, lines 5-6) is directly labeled in FIG. 4. "Porous tube 48 may be comprised of any suitable elastomeric material, such as PET or angioplasty balloons, that is capable of expanding and contracting, and that may be made fluid permeable" (column 5, lines 11-14). This is reiterated in claim 30: "...said support structure is comprised of a porous material" (column 11, lines 25-26) as well as claims 50 and 53-54. Thus, since the "support structure" mentioned in the claims is fluid permeable as implied by FIG. 4, and since the graft is permeable by nature, the first condition is met. (It should be noted that the embodiment in FIG. 5 lacks the expandable tube: the fluid is passed directly through the graft. (column 6, lines 19-23, 54-60), also satisfying the first condition.)

Also, it is made clear from the diagrams and descriptions that a pressure gradient is maintained in every embodiment of the patent. Cyclically pressurized fluid always flows through the lumen of the tissue: this is confirmed visually from the diagrams and verbally in the following descriptions: column 4, lines 19-20, 45-48; column 5, lines 40-46; column 5 line 66 - column 6 line 6. This pressure gradient is also

mentioned repeatedly in the claims. The first claim specifies “a means for imparting radial and shear stresses to said at least one vascular graft”. Thus, the second condition is met

It is therefore concluded that all embodiments depicted in the Dunkelman patent allow for transmural flow.

Figure 7.3 Effect of convection upon concentration distribution across membrane.



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It is also my opinion that my patent application guides the researcher in the field to establish an effective concentration gradient for the chemo-attractants. This would certainly be understood from certain statements in my patent application and from general knowledge. I refer below to these statements that discuss gradients and/or chemotaxis.

On page 8, the specification points out that the attractant induces movement, for example, by chemotaxis in response to the factors in the gradient, or haptotaxis where the factor is bound to the matrix in a

gradient, and that such activity is believed to contribute to localization of endothelial cells into an intimal layer in the invention, disclosing the importance of the concentration gradient.

The concentration of the factor that is chosen will, of course, vary with the factor. Accordingly, the concentration of the factors used to form the bi-layers is empirical and is based on such parameters as the factor itself, its activity, the density of the cells, the density of the matrix, specific formulation of the matrix, distance to the cells, and the like. Any such concentration can be determined by ordinary experimentation. Many assays are known in the art to assess the mitogenic or attractant activity of any particular factor. This is explained on page 13 of the application.

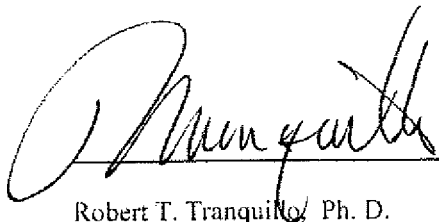
In Example 3, the specification discloses that ECs can be selectively localized to surfaces after incorporation (onto the matrix) by presenting a concentration gradient of VEGF, presumably via a chemotaxis response.

Accordingly, in my opinion, the ordinary researcher in the field, reading my application, would have realized that conditions must be such that the factors could develop an effective concentration gradient. Such a gradient would induce the endothelial cells to localize at the luminal surface by chemotaxis and/or proliferation, thereby forming the bi-layer.

Conclusion

It is my conclusion that the person of ordinary skill in the art would not have achieved the claimed invention by combining the Shum-Tim reference with the Dunkelman reference for the reasons that I have explained above.

All statements made herein of my own knowledge are true and all statements made on information believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


Robert T. Tranquillo, Ph. D.

7/2/10

Date

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ROBERT T. TRANQUILLO

Personal

Address: 1267 Wyncrest Court
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Born: 17 August 1957
Philadelphia, PA

Marital Status: Married, three sons, one daughter

Education: Postdoctoral Fellow, Oxford University 1986-1987
PhD (ChE) University of Pennsylvania 1986
MS (ChE) Stanford University 1980
BS (ChE) Pennsylvania State University 1979

Professional Experience

Professor and Head of Biomedical Engineering, University of Minnesota, July 2000 - present

Professor of Chemical Engineering, University of Minnesota, September 1998-present

Artificial Tissues Program Coordinator, University of Minnesota MRSEC, September 1998 - 2002

Associate Professor of Chemical Engineering, University of Minnesota, September 1993-1998

Assistant Professor of Chemical Engineering, University of Minnesota, September 1987-September 1993

Chemical Engineer (Chemical Engineering Laboratory, SRI International June 1980-June 1981

Chemical Engineer (Marshall Laboratory), E I du Pont de Nemours & Company, June 1979-September 1979

Chemical Engineer (Plastics Division), Rohm and Haas Kentucky, Incorporated, June 1978-September 1978

Academic Honors

Distinguished McKnight University Professor

Fellow of the Biomedical Engineering Society

Fellow of the American Institute for Medical and Biological Engineering

Shell Land Grant Chair in Chemical Engineering & Materials Science

NSF Presidential Young Investigator

McKnight-Land Grant Professor

NATO Postdoctoral Fellowship in Science and Engineering

EXXON Fellowship, University of Pennsylvania

University Fellowship, University of Pennsylvania

Graduate Engineering Fellowship, Stanford University

BS Highest Distinction, Pennsylvania State University

Research Interests

Mathematical models, *in vitro* and *in vivo* assays, and clinical applications of cell motility: cell migration (applied to wound healing and tissue engineering) - random migration, chemotaxis, contact guidance; soft tissue engineering (bioartificial artery, cardiovascular valve, and myocardium fabrication and functional characterization) - rheology, mechanics, fibril structure and cell compaction of cell/biopolymer constructs; magnetic induced collagen alignment (guided nerve regeneration); receptor-mediated cytom mechanics (cell shape change and locomotion); analytical and numerical analysis, stochastic processes; image processing and analysis.

Society Membership

Biomedical Engineering Society (Board of Directors 1998-2001, Publications Board, 2003-2010 (Chair 2008-2010), Executive Committee (2008-2010)), US National Committee on Biomechanics (AIChE Representative 1999-2003)

Publications

1. S. H. Zigmond, R. Klausner, R. T. Tranquillo, D. A. Lauffenburger, "Analysis of the Requirements for Time-Averaging of the Receptor Occupancy for Gradient Detecting by Polymorphonuclear Leukocytes," in *Membrane Receptors and Cellular Regulation*, eds. M. Czech and C. R. Kahn, Alan R. Liss, 347 (1985).
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79. Syedain, Z. H., Bjork, J.W., Sando, L. and R. T. Tranquillo, "Controlled compaction with ruthenium-catalyzed photochemical cross-linking of fibrin-based engineered connective tissue," *Biomaterials* 30:6695-701 (2009).
80. Weinbaum J. S. and R. T. Tranquillo, "Monitoring Collagen Transcription by Vascular Smooth Muscle Cells in Fibrin-Based Tissue Constructs," *Tissue Eng Part C* (accepted).
81. Huynh, T.H. and R. T. Tranquillo, "Fusion of concentrically layered tubular tissue constructs increases burst strength," *Ann Biomed Eng* 38:2226 (2010).
82. Weinbaum J. S., Tranquillo, R. T. and R. P. Mecham, "The Matrix-Binding Domain of Microfibril-associated Glycoprotein-1 Targets Active Connective Tissue Growth Factor to a Fibroblast-Produced Extracellular Matrix," *Macromol Biosci* (accepted).
83. Ahmann, K. A., Weinbaum J. S., Johnson, S. L. and Tranquillo, R. T., "Fibrin Degradation Enhances Vascular Smooth Muscle Cell Proliferation and Matrix Deposition in Fibrin-Based Tissue Constructs Fabricated In Vitro," *Tissue Eng Part A* (accepted).
84. Syedain, Z.H. and R. T. Tranquillo, "TGF- β diminishes collagen deposition during long-term cyclic stretching of engineered connective tissue: Role of decreased ERK signaling," (submitted).

Invited Talks

1. "Analysis of Leukocyte Chemosensory Movement," International Congress on the Biological and Clinical Aspects of Phagocyte Function, Pavia, Italy, September 1986.
2. "Stochastic Model of Leukocyte Chemosensory Movement," International Conference on Mathematical Models in Biology, Oberwalfach, FRG, March 1987.
3. "On Why Cells Don't Crawl in Straight Lines: Consequences of Stochastic Receptor Sensing of Chemical Concentrations," Gordon Conference on Oscillations and Dynamic Instabilities in Chemical Systems, Plymouth, New Hampshire, July 1988.
4. "Mechanisms of Leukocyte Chemosensory Movement," American Society for Gravitational and Space Biology Annual Meeting, Washington, D.C., October 1988.
5. "Models for Chemical Sensing," Workshop on Modeling, Analysis, and Simulation of Biological Motion Konigswinter, FRG, March 1989.
6. "Receptor-Regulated Motility of Leukocytes," International Conference on Mathematical Models in Biology, Oberwalfach, FRG, February 1990.
7. "Theory and Models of Gradient Perception," Symposium on Motility and Taxis, Society for General Microbiology Annual Meeting, York, England, December 1990.

8. "Stochastic Model of Chemotactic Receptor-Mediated Dynamic Morphology of Leukocytes," Symposium on Some Mathematical Questions in Biology, American Society of Cell Biology Annual Meeting, Denver, Colorado, November 1992.
9. "Quantitative Tissue Engineering," NIGMS Meeting on Research Opportunities in Biomolecular Engineering: The Interface Between Chemical Engineering and Biology, Washington, D.C., December 1992.
10. "Biphasic Theory and *In Vitro* Assays of Cell-Fibril Mechanical Interactions in Tissue-Equivalent Collagen Gels," Second World Congress of Biomechanics, Amsterdam, The Netherlands, July 1994.
11. "Anisotropic Biphasic Model of Cell-Fiber Mechanical Interactions," Workshop on Cell and Tissue Motion—Models, Analysis and Simulation, Bonn-Rottgen, Germany, March 1995.
12. "Magnetically-Oriented Tissue-Equivalent Tubes: Application to a Circumferentially-Oriented Media Equivalent," Second International Conference on Cellular Engineering, La Jolla, CA, August 1995.
13. "An Anisotropic Biphasic Theory of Tissue-Equivalent Mechanics: The Interplay Among Cell Traction, Fibrillar Network Deformation, Fibril Orientation and Cell Contact Guidance," Gordon Research Conference on Bioengineering and Orthopedic Science, Andover, New Hampshire, August 1996.
14. "Manifestations of Cell Motility in Tissue-Like Gels," Workshop on Cell Mechanics, Atlanta, GA, November 1996.
15. "Circumferential Alignment and Mechanical Stiffening of Media-Equivalents," Workshop on Biomaterials and Tissue Engineering, Hilton Head Island, S. Carolina, February 1997.
16. "Self-Organization of Tissue-Equivalents: The Nature and Role of Contact Guidance," 4th Abercrombie Symposium on Cell Behaviour: Control and Mechanism of Motility, Oxford, England, September 1997.
17. "Fabrication of a Tissue-Equivalent Cardiovascular Valve," Minisymposium on Tissue Engineering, 1999 BMES/EMBS Annual Meeting, Atlanta, GA, October 1999.
18. "Engineered Alignment of Self-Assembled Biopolymers for Artificial Tissues," CFMR Symposium on Polymers and Biopolymers, Michigan State University, February, 2000.
19. "Biomechanical Issues in Artificial (Soft) Tissue Fabrication from Cell-Contracted Biopolymers," Functional Tissue Engineering Workshop, Tampa, September, 2000.
20. "The Tissue Engineered Small Diameter Artery," BECON Symposium on Reparative Medicine: Growing Tissues and Organs, Vascular Assembly Panel, Washington, D.C. June, 2001.

21. "Cell-remodeled biopolymers with engineered alignment." GRC on Biomaterials and Tissue Engineering, Plymouth, NH, July 2003.
22. "In Vitro Tissue Growth and Development In Fibrin Gel Remodeled By Neonatal and MAPC-derived Smooth Muscle Cells." Regenerate, Seattle, WA, June 2004.
23. "Cardiovascular Tissue Engineering Based on Controlled Cell Remodeling of Biopolymers." Clemson/MUSC/USC Bioengineering Colloquium, October 2004.
24. "Cardiovascular Tissue Engineering Based on Controlled Cell Remodeling of Biopolymers." Area 15 d/e Plenary Lecture, AIChE Annual Meeting, Austin, TX November 2004.
25. "Paradigm for Self-Organized Tissue Growth: Cell-Mediated Fibrin Gel Contraction, Alignment, and Remodeling." Regenerate, Atlanta, GA, June 2005.
26. "In Vitro Tissue Growth & Development in Fibrin Gel Remodeled by Smooth Muscle Cells." Experimental Biology, San Francisco, CA, April 2006.
27. "Exploiting contact guidance for guided nerve regeneration and growth of aligned cardiovascular tissues." EMBO/IGB Meeting - Workshop on Cell Migration, Tissue Invasion And Disease, Capri, Italy, October 2006.
28. "Cardiovascular Tissue Engineering Based on Controlled Cell Remodeling of Biopolymers." 5th Annual Gene Therapy Symposium for Heart, Lung, and Blood Diseases: Tissue Engineering and Regenerative Medicine, Sonoma, CA, November 2006.
29. "Towards tissue-engineered grafts via controlled cellular remodeling of fibrin gel tubes." NAVBO Vascular Matrix Biology and Bioengineering Workshop, Whistler Village, BC, Canada, March 2007.
30. "Cardiovascular Tissue Engineering Based on Controlled Cell Remodeling of Biopolymers." Center for Vascular Remodeling and Regeneration, University of Pittsburgh, Pittsburgh, PA, May 2007.
31. "Effects of Cyclic Distension on Fibrin-Based Tubular Tissue Constructs." TERMIS-NA, Toronto, CA, April 2007
32. "Cardiovascular Tissue Engineering Based on Controlled Cell Remodeling of Biopolymers." TERMIS-EU, London, UK, September 2007
33. "Cardiovascular Tissue Engineering Based on Cell-Remodeled Fibrin." 2008 Annual BMES Meeting, St. Louis, MO, September 2008
34. "Vascular Tissue Engineering Based on Cell-Remodeled Fibrin." 2008 Annual BMES Meeting, St. Louis, MO, September 2008

35. "Flow Responses of Blood Outgrowth Endothelial Cells in Vascular Tissue Engineering." Experimental Biology Annual Meeting, New Orleans, LA, April 2009
36. "Fibrin-based Tissue Engineering." Wound Healing Society Annual Meeting, Dallas, TX, April 2009
37. "Towards A Completely Biological Living Heart Valve Replacement." IEEE-EMBS Annual Meeting, Minneapolis, MN, September 2009

Seminars

1. SRI International, Chemical Engineering Laboratory, November 1984.
2. University of California, Berkeley, Department of Chemical Engineering, February 1985.
3. University of Rochester, Department of Chemical Engineering, April 1985.
4. University of Minnesota, Department of Chemical Engineering, April 1985.
5. Penn State University, Department of Chemical Engineering, May 1985.
6. New Jersey Institute of Technology, Department of Chemical Engineering, April 1986.
7. King's College, MRC Cell Biophysics Unit, October 1986.
8. University of Oxford, Mathematical Institute, October 1986.
9. University of Glasgow, Department of Cell Biology, December 1986.
10. University of Oxford, Developmental Biology Group, February 1987.
11. University of Heidelberg, Institute of Applied Mathematics, February 1987.
12. University of Strathclyde, Department of Mathematics, May 1987.
13. The Slade Hospital, Dermatology Department, June 1987.
14. University of Minnesota, Department of Microbiology, January 1988.
15. University of Minnesota, Department of Oral Biology, January 1988.
16. The Procter & Gamble Company, December 1989.
17. University of Minnesota, Biophysics Program, December 1989.
18. University of Minnesota, Biomedical Engineering Program, December 1989.
19. University of Minnesota, Dept. of Genetics Cell Biology, April 1990.
20. The Procter & Gamble Company, February 1991.
21. The Shriners Burns Institute, February 1991.
22. University of Bonn, Bonner Biomathematics Colloquium, May 1991.
23. University of Bonn, Institute for Applied Mathematics, May 1991.
24. Rice University, Department of Chemical Engineering, March 1992.
25. University of Illinois, Department of Chemical Engineering, April 1992.
26. The Procter & Gamble Company, June 1992.
27. University of Bonn, Bonner Biomathematics Colloquium, March 1994.
28. University of Bonn, Institute for Applied Mathematics, March 1994.
29. Johns Hopkins University, Department of Chemical Engineering, July 1994.
30. Duke University, Department of Biomedical Engineering, February 1995.
31. The University of Wisconsin--Madison, Department of Chemical Engineering, September 1995.
32. Massachusetts Institute of Technology, Department of Chemical Engineering, December 1995.
33. The University of Florida, Department of Chemical Engineering, March 1996.
34. Johns Hopkins University, Department of Chemical Engineering, April 1996.
35. University of Pennsylvania, Department of Chemical Engineering, December 1997.

36. Rutgers University, Department of Chemical Engineering, December 1997.
37. University of Colorado, Department of Chemical Engineering, October 1998.
38. Iowa State University, Department of Chemical Engineering, November 1998.
39. University of Virginia, Department of Biomedical Engineering, May 1999.
40. Penn State University, Department of Chemical Engineering, November 1999.
41. Washington University, Department of Biomedical Engineering, May 2000.
42. Harvard University, Division of Engineering and Applied Science, June 2001.
43. University of Pennsylvania, Department of Biomedical Engineering, November 2001.
44. Northwestern University, Department of Biomedical Engineering, January 2002.
45. Johns Hopkins University, Center for Computational Medicine and Biology, April 2002.
46. NC State University, Department of Chemical Engineering, November 2002.
47. University of Michigan, Department of Biomedical Engineering, November 2003.
48. University of Virginia, Department of Biomedical Engineering, November 2003.
49. University of Pittsburgh, McGowan Institute for Regenerative Medicine, January 2004.
50. 3M Tech Forum, Life Sciences Chapter, July 2004.
51. MIT, Division of Bioengineering (Inaugural Medtronic BME Distinguished Lecture), November 2004.
52. Boston University, Department of Biomedical Engineering (Distinguished Chairs and Scientists Series), November 2004.
53. Rice University, Department of Bioengineering, November 2004.
54. University of Wisconsin-Madison, Department of Chemical Engineering, October 2005.
55. RPI, Department of Biomedical Engineering, November 2005.
56. Columbia University, Department of Biomedical Engineering, November 2005.
57. University of Texas-Austin, Department of Biomedical Engineering, November 2005.
58. Medical College of Wisconsin, Department of Physiology, November 2006.
59. University of Toronto, IBBME ("Distinguished Speakers in Bioengineering" lecture series), April 2007.
60. Purdue University, Department of Biomedical Engineering, November 2007.
61. Duke University, Department of Biomedical Engineering, December 2007.
62. Clemson University, Department of Biomedical Engineering, February 2008.
63. Wake Forest Institute of Regenerative Medicine, October 2008.
64. FIBR Team Winter Conference, February 2009.
65. University of Houston, Department of Chemical and Biomolecular Engineering, October 2009.
66. Rice University, Department of Bioengineering, November 2009.
67. CMU University, Department of Chemical and Biomolecular Engineering, November 2009.
68. UC-Davis, Department of Biomedical Engineering, January 2010.

Research Support (only PI/co-PI grants listed)

UMN/Mayo Partnership in Biotechnology and Medical Genomics "Cell Therapy of Cardiac Arrhythmias" 828,040 (total costs) 1/01/2009 - 12/31/2010 (co-PI with D. Packer, Mayo)

NIH/NHLBI 1 R01 HL083880 "Engineered Artery Growth in Vitro Based on Cell-Remodeled Fibrin" 4,308,044 (total costs) 6/01/2006 - 5/31/2011

NIH/NHLBI 1 R01 HL071538 Biomedical Engineering Research Partnership "Tissue-engineered Valve from Cell-Remodeled Biopolymer" 4,151,853 (total costs) 6/01/2003 - 5/31/2008

NIH/NIBIB R21 EB00989 "Biopolymer-mimetic Worm-like Micelle Tissue Scaffolds" \$150,000 (annual direct costs) 10/1/02-9/30/05

NIH/NHLBI R01 HL60495-01A1 "Development of a Bioartificial Artery" \$205,000 (annual direct costs) 4/1/99-3/31/03

Supplement to Program Project NIH/GM-50150 (PI: Caldwell, M. D.), "Fibroblast Migration-Traction Correlation and Wound Strengthening" \$154,258 (total direct costs) 8/1/99-7/31/00

NSF/MDC/CCR-9527151 (PI: Petzold, L. R.), "A High-Performance Problem Solving Environment for Optimization and Control of Chemical and Biological Processes," \$47,000 (direct costs to RTT annually), October 1995-September 2000.

Supplement to Program Project NIH/GM-50150 (PI: Caldwell, M. D.), "Characterizing the Mechanisms and Regulation of Wound Resolution *In Vitro*," \$244,028 (total direct costs), August 1996-July 1999.

NSF/BES-9522758, "Magnetically-Oriented Tissue-Equivalents: Mathematical Model and Application," \$344,988 (total direct costs), October 1995-September 1998.

NIH/STTR (PI: Garg, A. K., Integra Life Sciences), "Nerve Regeneration Using Magnetically Aligned Collagen," \$45,871 (direct costs to RTT), April 1997-March 1998.

NSF/BBS Research Training Group Program, (co-PI's: Tirrell, M. V. and Furcht, L. T.), "Characterization of Cell Behavior in Biological Matrices," \$66,000 (direct costs to RTT in 1998/1999), August 1994-September 1999.

NIH First Independent Research Support and Transition (FIRST) Award, "Predictive Model and *In Vitro* Assay of Wound Healing and Contraction", \$495,200, April 1991-May 1996.

NSF Presidential Young Investigator Award NSF/BCS-8957736, \$125,000 (to \$500,000 with matching funds provision), October 1989-September 1994.

University of Minnesota McKnight-Land Grant Professorship, \$102,000, June 1989-June 1992.

NSF Research Initiation Award NSF/EET-880969, "The Neutrophil Model for Growth Factor Signalling," \$70,000, June 1988-June 1990 (University matching funds of \$10,000).

NSF Engineering Research Equipment Grant NSF/EET-8807691, "Image Analysis for Automated Microscopy," \$58,000 (University matching funds of \$29,000).

ACS Institutional Research Grant IN-13-29-8, "Verification of a Mathematical Model of the Collagen Gel Invasion Assay," \$5,000, December 1988-December 1989.

Graduate School Grant-in-Aid, "Experimental Verification of a Model for Cell Mechanical Interactions with Materials," \$8,000, December 1988-June 1989.

Other Support

Whitaker Foundation Special Opportunity Award, "Lab-based Courses for BME Undergraduates and Practicing Engineers," \$999,432 (total costs), 11/1/01-10/31/04.

Patents

"Tissue-Equivalent Approach to a Tissue-Engineered Cardiovascular Valve" U.S. Patent #6,666,886 (with T. Girton and M. Neidert)

"Magnetically Oriented Tissue-Equivalent and Biopolymer Tubes" U.S. Patent #5,948,654 (with D. Mooradian, S. Guido, and T. Girton)

"Tissue-Equivalent Rods Containing Aligned Collagen Fibrils and Schwann Cells" U.S. Patent #6,057,137 (with S. Guido)

University Service

Program Advisory Committee for the Biomedical Engineering Graduate Program, 1989.

Search Committee for the Earl Bakken Endowed Professorship in Biomedical Engineering, 1989-1991, 2002-2003.

Senate Committee on Computing and Information Services, 1990-1992.

Minnesota Supercomputer Institute Undergraduate Internship Committee, 1994-1995.

University Senate, 1995-1996.

Graduate School Fellowship Committee, 1996.

Search Committee for the Director of Development for the Institute of Technology, 1995-1996.

Graduate Recruiting Committee, Department of Chemical Engineering & Materials Science, 1987-2000.

Acting Director of Undergraduate Studies, Department of Biomedical Engineering, 1998-1999, 2003-2004.

Director of Graduate Studies, Department of Biomedical Engineering, 2000-2003, 2005-2006.

Search Committee for Director of the Cancer Center, 2004-2005.

Ad Hoc Committee on Biomedical Engineering and Medical Devices (Chair), 2005-2006.

Strategic Positioning Task Force on Undergraduate Reform: Honors, 2005.

Search Committee for Director of the Medical Device Center (Chair), 2007.

University Programs

President's Distinguished Faculty Mentor Program, 1990-1991, 1999-2004, 2007-2009.

Bush Foundation Program for Excellence in Teaching, 1991-1992.

Steering Committee for the Christian Faculty-Staff Network, 1987-1995.

Biomedical Engineering Institute, Associate Director for Research, 1996-1998.

Biointerfacial Engineering Program, Principal Investigator, 1991-1998.

Minnesota Supercomputer Institute, Associate Fellow, 1994-2002.

MRSEC Artificial Tissues Program (Leader), 1998-2002.

Institute for Engineering in Medicine, Member, 2000 - present

Courses Taught

ChE 100 - Introduction to Chemical Engineering, University of Pennsylvania, Fall 1983 (as Exxon Fellow).

BME 3101 - Biomedical Transport Processes, Spring 2001, Fall 2001, Spring 2003, Spring 2004, Spring 2005, Spring 2006, Spring 2008, Spring 2009, Spring 2010

BME 5910 - Biomedical Transport Processes, Spring 1997, Spring 1998, Spring 1999, Spring 2001

BME 5311/ChE 5753 - Biomedical Transport Processes, Spring 2000

BME 5920 - Cell Engineering, Spring 1997.

ChE 3001 - Programming for Computational Methods, Winter 1992.

ChE 5001 - Computational Methods in Chemical Engineering and Materials Science, Spring 1988, Fall 1988, Spring 1989, Spring 1990, Fall 1990, Spring 1992, Spring 1993, Fall 1993, Spring 1994, Fall 1995.

ChE 5103 - Heat and Mass Transfer, Spring 1995.

ChE 5401 - Unit Operations Laboratory, Spring 1995.

ChE 5601 - Process Control, Winter 1995, Winter 1996, Winter 1997, Winter 1999.

ChEn 4601 - Process Control, Spring 2000.

ChEn 8901 - Engineered Soft Tissues, Spring 1996.

ChEn 8903 - Cellular Bioengineering, Fall 1989, Fall 1992, Fall 1994.

ChEn 8004 - Transport Phenomena, Winter 1988, Winter 1989, Winter 1990, Winter 1992.

ChEn 8301 - Transport Phenomena, Fall 1999.

Graduate Student Theses Directed

Mohammad Durrani (M.S.): Mathematical modeling of biomechanical phenomena in wound contraction (August 1991).

James Pray (M.S.): Characterization of an *In Vitro* wound healing assay (January 1991) (Plan B project in Biomedical Engineering Graduate Program).

Stefano Guido (M.S.): Quantitative characterization of contact guidance exhibited by fibroblasts in collagen gels using birefringence (February 1991).

Richard Dickinson (Ph.D.): Quantitative analysis and mathematical models of receptor-mediated tumor cell invasion, migration and haptotaxis (October 1992).

Alice Moon (Ph.D.): Cell traction forces exerted on the extracellular matrix: Modeling and measurement (December 1992).

Prabhas Moghe (Ph.D.): Phenomenological and mechanistic analyses of leukocyte chemotaxis (September 1993).

Victor Barocas (Ph.D.): Anisotropic, biphasic modeling of cell-collagen mechanical interactions in tissue equivalents (January 1996).

James Schneider (Ph.D.): Direct Measurement of Forces Between Bilayer-bound Cell Adhesion Elements and Control of Cell Adhesion to Substrata by Surface Modification (December 1997) (jointly advised by M. Tirrell).

Timothy Girton (Ph.D.): Tissue Engineering an Arterial Media-Equivalent (May 1999).

David Knapp (Ph.D.): Cell Migration and Traction in Tissue-Equivalents and an *In Vitro* Assay for Wound Healing (August 1999).

Narendra Dubey (Ph.D.): Contact Guidance of Neurites with Application to Nerve Regeneration (December 1999).

Mihir Wagle (Ph.D.): Transport Models for Tissue Cells (June 2000).

Theodore Tower (Ph.D.): Polarimetric Characterization of Tissues and Biopolymer Gels (June, 2000).

Benjamin Rosner (M.D./Ph.D.): Contact Guiding Neurotrophic Collagen Gel Rods for Peripheral Nerve Regeneration (April, 2001).

Evie Lee (M.S.): *In Vitro* Remodeling for Improved Tissue-Equivalents (June, 2001).

Paul Enever (Ph.D.): Fibroblast Traction and Migration in Collagen and Fibrin: Biomechanical and Biochemical Influences on Wound Healing (July, 2001).

Jennifer Long (M.D./Ph.D.): Elastogenesis in Cardiovascular Tissue-Equivalents (July, 2002).

Jeff Ross (M.S.): Gene Expression in Cardiovascular Tissue-Equivalents (August, 2002).

Erin Grassl (Ph.D.): Enhancing the Properties of the Medial Layer of a Bio-Artificial Artery (November, 2002).

Michael Neidert (Ph.D.): Tissue Engineering a Cardiovascular Valve (April, 2003).

Audrey Gandadjaja (M.S.): "Enhancement of Entubulation Repair with Schwann Cells" (September, 2004).

Brett Isenberg (Ph.D.): The Roles of Mechanical Signaling in the Development of a Bio-Artificial Artery (May, 2005).

Sumeet Jain (Ph.D.): Synthesis of Biopolymer-mimetic Worm-like Micelle Tissue Scaffolds (August, 2005).

Bradley VanWinkle (M.S.): Characterization of Biopolymer-mimetic Worm-like Micelle Tissue Scaffolds (November, 2005).

Jason Meyers (M.S.): "Development of a Tissue-Engineered Myocardial Patch" (August, 2006).

Paul Robinson (Ph.D.): "Development of a Functional Tissue-Engineered Heart Valve Replacement" (December, 2007).

Zeeshan Syedain (Ph.D.) "Controlled Stretching Bioreactor for Development of a Tissue-Engineered Heart Valve" (April, 2009).

Katie Ahmann (Ph.D.) "Mechanical Conditioning of Fibrin-Based Bioartificial Arteries" (expected completion October, 2010).

Jason Bjork (Ph.D.) "Feedback Controlled Radial Perfusion Bioreactor System for Tissue Engineered Blood Vessels" (expected completion December, 2010).

Kristen Thatcher (Ph.D.) "The Development of a Microvascular Network within a Tissue Engineered Myocardium" (expected completion August, 2012).

Trevor Huynh (Ph.D.) “Multi-Stage Cell Seeding and Mechanical Conditioning of Fibrin-Based Bioartificial Arteries” (expected completion August, 2011).

Richard Beck (Ph.D.) “A Systems Biology Rationale for In Vitro Tissue Growth Optimization” (expected completion August, 2012).

Jared Heirman (Ph.D.) “TBD” (expected completion August, 2013).

Nathan Weidenhamer (Ph.D.) “TBD” (expected completion August, 2013).

Victor Lai (Ph.D., co-advised by V. Barocas) “Modeling of Bioengineered Tissue Mechanics” (expected completion August, 2013).

Jill Schmidt (Ph.D.) “TBD” (expected completion August, 2014).

Jackie Wendall (Ph.D.) “TBD” (expected completion August, 2014).

Postdoctoral Students Supervised

David Shreiber (Ph.D. BioE, University of Pennsylvania) 1998 - 2002

Stacey Dixon (Ph.D. ME, Georgia Tech) 2000 – 2002

Chrysanthi (Sandy) Williams (Ph.D. BME, Georgia Tech) 2004 – 2005

Choon-Sik Jhun (Ph.D. BME, Texas A&M) 2005 – 2007.

Lauren Black (Ph.D. BME, Boston University) 2006 – 2009.

Justin Weinberg (Ph.D. Molecular Biology, Washington University) 2007 – present.

Zeeshan Syedain (Ph.D. ChEn, University of Minnesota) 2009 – present.

Graduate Faculty Membership

Biomedical Engineering

Biomedical Science

Chemical Engineering

Materials Science and Engineering

Mechanical Engineering